Before the FEDERAL COMMUNICATIONS COMMISSION Washington, D.C. 20554

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To: The Commission

COMMENTS OF THE CRITICAL CARE TELEMETRY GROUP

The Critical Care Telemetry Group ("CCTG"), which consists of Hewlett-Packard Company Medical Products Group ("HP"), Marquette Electronics, Inc., Pacific Communications, Siemens Medical Systems, Inc., and SpaceLabs Medical, Inc. ("SpaceLabs"), hereby responds to the Notice of Inquiry ("NOI"), FCC 94-97, released in the above-captioned matter on May 4, 1994.

The CCTG represents essentially all of the companies located in the U.S. that are engaged in the production of low-power, portable biomedical telemetry systems. This technology, which may be used to monitor a variety of vital patient parameters, is in use in every major hospital and healthcare facility in the country. As previously has been demonstrated for the Commission, the continued use of these systems is directly threatened by increasing congestion and interference in the bands presently employed by these devices: 174-216 MHz, see

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An extensive discussion of these systems and their vital role in the delivery of cardiac care appears in the separate comments filed by HP and SpaceLabs in PR Docket No. 92-235. Copies of HP's and SpaceLabs' comments are attached hereto as, respectively, Appendices A and B.

See, e.g., Appendix A at 5; Appendix B at 5-9.

47 C.F.R. § 15.241, and 450-470 MHz, see id., §§ 90.75, 90.217, $90.267.\frac{3}{}$

Congress expressed its concern regarding this dilemma by directing both NTIA and the Commission to make special provision for the expanding spectrum needs of biomedical telemetry. In the NOI, at ¶9(g), the Commission recognizes that Congressional mandate and inquires as to whether the frequencies under consideration in this proceeding are appropriate for low-power biomedical telemetry and, if so, should special accommodation be made for such systems in the allocation of the subject spectrum.

All of the frequencies presently under consideration are above 2 GHz. For technical reasons previously identified for the Commission, ⁵/ low-power biomedical telemetry systems must operate below 1,000 MHz. Thus, the spectrum under consideration in the <u>NOI</u> is not appropriate for allocation for these essential

Biomedical telemetry systems also are authorized to operate in the 512-566 MHz band under 47 C.F.R. § 15.209(g)(2). However, the power levels permitted to be used in that band are far too low to permit these systems to function.

See Conference Report on the Omnibus Budget Reconciliation Act of 1993, 103d Cong., 1st Sess., Rpt. No. 103-213 (1993), at 479.

 $[\]underline{5}$ See, e.g., Appendix B at 3-5.

healthcare services. If it were otherwise, the Commission obviously would be obliged to heed Congress' unambiguous mandate.

Respectfully submitted,

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June 15, 1994

Before the FEDERAL COMMUNICATIONS COMMISSIC Washington, D.C. 20554

In the Matter of)	
)	
Replacement of Part 90 by Part 68 to)	PR Docket No. 92-235
Revise the Private Land Mobile Radio)	
Services and Modify the Policies)	
Governing Them)	

COMMENTS OF HEWLETT-PACKARD COMPANY

Hewlett-Packard Company ("HP") hereby submits the following comments with respect to the Notice of Proposed Rulemaking in the above-captioned proceeding.¹

I. <u>OVERVIEW</u>

The Commission's <u>Notice</u> presents two basic, underlying goals with respect to the "refarming" of private land mobile frequencies below 512 MHz, each of which HP wholeheartedly supports: <u>first</u>, to require systems that operate in these bands to be spectrum efficient; and, <u>second</u>, to take advantage of such spectrum efficient use, over time, to reorganize and make more compatible the allocation of frequencies among services within the bands, ultimately to improve the quality and availability of service in this crowded spectrum.

HP is concerned, however, that the Commission's proposal does not fully serve these goals. In particular, certain of the proposals made by the Commission and other proposals submitted in this proceeding by the Land Mobile Communications Council ("LMCC")² will have a destructive impact upon low-power electrocardiogram ("ECG") and other medical telemetry technologies, which operate primarily on offset or "splinter" frequencies in the 450-470 MHz band. This unintended effect would occur despite the fact that these essential, life-saving medical devices already meet, for all practical purposes, the efficiency standards proposed by the Commission for 2004.

¹ By Order, DA 93-145, released February 9, 1993, the period for filing initial comments in response to the <u>Notice</u> was extended until May 28, 1993.

² LMCC calls its proposal, submitted April 28, 1993, a "Consensus Plan."

Furthermore, the problem for ECG and other medical telemetry devices is not one that can be resolved by making their operation more efficient. In this regard, while the issue of transition time to more efficient systems is of great importance to some users of the band, for medical telemetry operations, the current proposals offer nothing to which to transition. Fundamentally, low power medical telemetry devices will be forced out of the 450-470 MHz band unless a reserved portion of the band is created for their primary use and new high power operations on or within 12.5 kHz of the 450-470 MHz frequencies currently available for low power medical telemetry devices (*see* Note 3 below) are forbidden until hospitals are given a sufficient time period to relocate those devices to the new frequencies.

II. LOW-POWER MEDICAL TELEMETRY OPERATIONS IN THE 450-470 MHz BAND PERFORM ESSENTIAL, LIFE-SAVING SERVICES. THESE DEVICES MUST BE DESIGNED TO MEET THE SPECIAL REQUIREMENTS OF CARDIAC PATIENTS IN A HOSPITAL ENVIRONMENT.

For the last twenty years, HP has pioneered the development of highly efficient, low-power miniaturized ECG devices that enable hospitals to monitor the vital signs of cardiac patients, while permitting the patients to become ambulatory within hospital areas. Such early ambulation with continuous electronic monitoring shortens recovery time and reduces healthcare costs. These devices operate at exceedingly low power (currently 2-4 mW) on over 250 offset and other channels³ in the 450-470 MHz band; at some hospitals, over 200 telemetry channels may be in operation at the same time, and several hospitals have requirements that exceed present channel capacity limits.

The special requirements associated with monitoring the vital signs of cardiac patients has mandated a number of design features in the ECG device.⁴ Among other

³ Most of the frequencies used for ECG devices in the 450-470 MHz band are offset frequencies available for Business Radio use under 47 C.F.R. § 90.267. A limited number of these offset frequencies are available specifically for biomedical telemetry operation under 47 C.F.R. § 90.238(e). In addition, twelve primary channels in the Business Radio service that are restricted to 2 watts or less may be employed. See 47 C.F.R. § 90.75(b)(4).

⁴ A more detailed description of these devices and technical considerations associated with their design is set forth in HP's Comments, filed January 15, 1992, to the Commission's Notice of Inquiry, Spectrum Efficiency in the Private Land Mobile Radio Service Bands in Use Prior to 1968, PR Docket No. 91-170, that preceded the Notice.

things, the need for instantaneous, continuous and error-free transmissions precludes the use of communications techniques that can accept a certain level of error or an occasional garbled transmission that might fail to alert a monitoring nurse of a life-threatening cardiac arrhythmia or which might distort other vital signs, such as heart rate, blood gas and blood pressure.

In addition, because transmitting units are to be worn by cardiac patients, it is essential that they be lightweight and protect patients from high levels of RF exposure. Low-power operation and other design features also preserve battery life and allow frequencies to be reused by other low-power medical telemetry devices at nearby locations. The antennas that monitor the patient units must be highly sensitive to receive signals from numerous patients within short distances. Unfortunately, this also makes the receive antennas highly sensitive to interference from outside sources. Finally, given the ever increasing concern in the United States regarding rising health care costs, the system has been and must be designed to be relatively inexpensive to purchase and to allow for a long period of use without equipment replacement.

III. SUBJECT TO MINOR CLARIFICATIONS TO THE PROPOSED RULES, MEDICAL TELEMETRY DEVICES ALREADY MEET THE EFFICIENCY STANDARDS PROPOSED FOR THE YEAR 2004. REDUCING AUTHORIZED BANDWIDTH WILL NOT MAKE ECG DEVICES MORE EFFICIENT.

Working within the constraints of 12.5 kHz offset frequencies, the ECG devices developed by HP for operation in the 450-470 MHz essentially already meet the efficiency requirements proposed by the FCC to be implemented in the year 2004. See proposed rule 47 C.F.R. § 88.433 applicable to "non-standard bandwidths." Thus, the ECG transmits a digital signal at 9600 band with an occupied bandwidth that is less than 10 kHz.

The one qualification to HP's analysis of the operation of the ECG under the proposed rules is that the product can be assured of meeting the emission mask proposed in Section 88.421(c) only when operated between 10 and 40 degrees centigrade. Because the ECG has been designed to be worn by hospital patients, it has not been necessary to prevent such out of band emissions at the more extreme

temperatures, which would be required for testing under 47 C.F.R. § 2.995.⁵ It would, moreover, require an increase in the size and weight of the device and decrease in battery life to meet the proposed emission mask requirement at such extreme temperatures.

Given the ordinary use of the product, the added shielding effect of the hospital environment and ECG's low power, there is no realistic possibility that the hypothetical failure of certain ECG devices operating at extreme temperatures to exceed mask limits will interfere with other users of the band. Accordingly, HP suggests that proposed Section 88.421(c) be modified, either to include an exception for low power devices as set forth in current section 90.217, or otherwise to provide that low power devices designed to be worn by medical patients need only meet emission mask levels as measured at temperatures ordinarily maintained in hospital environments.

HP has spent years designing ECG monitors to operate efficiently within the very limited spectrum available for its use and has analyzed various options including narrowband signaling and spread spectrum technologies and found none as efficient or effective as the current high-speed digital wide band ECG technology that is being employed. Requiring a reduction in bandwidth would not make the ECG more efficient. Among other things, in order to preserve the integrity of the data signal in a narrower bandwidth, a much-higher powered, heavier, and more expensive device would be required, all of which are incompatible with cardiac patient needs.

Alternatively, a lower data rate and/or excessive error in the data transmission stream would have to be accepted for narrowband operations — but none of this can be accepted without risking patients lives. Higher-powered units would also limit the ability for frequencies to be reused within fairly close proximity as is now the case, thereby creating greater frequency demands for such medical telemetry devices and an overall loss in spectrum efficient use.

⁵ Because of the product's low power, its emissions have been permitted under 47 C.F.R. § 90.217.

IV. INTERFERENCE FROM HIGH POWER SYSTEMS OPERATING AT 12.5 kHz SEPARATION FROM LOW POWER OFFSET FREQUENCIES IS ALREADY A MAJOR PROBLEM. THE PROPOSED NARROWBAND CHANNELIZATION PLANS WOULD CREATE AN INTOLERABLE LEVEL OF INTERFERENCE FOR ECG AND OTHER MEDICAL TELEMETRY DEVICES.

An increasing problem for hospitals employing ECG devices is interference from other incompatible operations on the same and adjacent frequencies. Increased frequency congestion in urban areas has made it more and more difficult for hospitals to find usable frequencies for ECG monitors. HP spends thousands upon thousands of dollars on service calls to hospitals each year attempting to locate available frequencies and replace crystals in units accordingly. While, in one sense, the interference problems that have been experienced by ECG devices are not unlike the problems experienced by other users of this congested band, the potential cost of lost or garbled transmissions of the vital signs of a cardiac patient that can be caused by such interference is incalculably higher. For this reason, HP has supported the Commission's refarming effort to create a more efficient and interference-free environment for communications devices that operate in the 450-470 MHz band.

Unfortunately, the narrowband frequency plan proposed by the Commission threatens vastly to increase the level of interference for ECG technology from many more sources from more closely adjacent and, indeed, overlapping channels. Increasing the number of potential users in the band by up to four times, particularly if such users employ digital data systems that require more continuous spectrum use, will have the unavoidable effect of increasing the interference environment already suffered by ECGs. Indeed, while the proposed plan legally would permit the continued operation of comparably (or more) efficient wide band systems, the narrowband channelization plan could have the effect of placing other users in such close frequency proximity to spectrally-efficient wide band systems that the occupied bandwidths of these new narrowband systems would overlap wide band channels, creating destructive interference.

The alternative "Consensus Plan" submitted by LMCC to authorize highpowered operations on offset frequencies would also make ECG operations on these channels impossible. The simple fact is that ECG monitors could not effectively operate on the same frequency as such high powered systems. LMCC suggests that some unspecified number of offset channels might remain for low power operation.⁶ Any reduction in the number of potentially available offset channels for ECG units, however, combined with increasing congestion in the band, would worsen the growing problem of locating an adequate number of interference-free channels for ECG and other medical telemetry technologies in frequency-congested urban areas or make it impossible. In this regard, not only is there a risk that currently available ambulatory care for heart patients likely have to be curtailed, there will be no room at all for new applications for more sophisticated medical telemetry devices that are currently being developed. These new technologies would increase the types and amount of data delivered to give doctors a more complete picture of a patient's physiological signs.

V. A PORTION OF THE BAND SHOULD BE RESERVED FOR LOW POWER MEDICAL TELEMETRY OPERATIONS.

After reviewing the Commission's proposals and other proposals that have already been filed in this proceeding and participating in panel discussions regarding refarming, which have been sponsored by the FCC, HP is convinced that the only long-term viable solution for ECG and other medical telemetry technologies in the 450-470 MHz band is to carve out a portion of the band for low-power medical telemetry use. In this regard, HP finds some elements of NABER's proposal to realign the band so that like services can operate on contiguous bands⁷ to be attractive. However, rather than simply dividing the band in accordance with the business purpose of the use; e.g., various types of industrial, land transportation, and other businesses, HP urges that a specific carve-out must be created for low-power medical telemetry devices. In this regard, such devices are no more compatible with voice communications from hospital ambulances than with those from taxis.

⁶ See "Consensus Plan" at 8.

⁷ HP agrees with NABER that such contiguous bands will be helpful for wide-band systems which, as NABER points out, may be better suited (and more efficient) for some applications than narrowband channels. See NABER "White Paper," filed May 4, 1993, at 1-2. There appears to be some inconsistency in NABER's recognition that wide band channels may be the most appropriate and efficient method for the delivery of digital data service and its proposal that the Commission cease authorizing applicants for new systems on more than 12.5 kHz channels. Consistent with the basic thrust of NABER's paper, HP urges that any such prohibition expressly except wide band operations that meet the Commission's efficiency standards for non-standard bandwidths.

Furthermore, NABER's emphasis on the license application and renewal process as a means of migrating systems and for establishing areas of exclusive use will not work for medical telemetry devices. Among other things, such devices, because of their low-power and lack of interference causing potential, have been generally delicensed. Furthermore, the nature of the use of these devices by individual hospitals is not one that fits within the parameters usually employed for considering the loading of mobile units on an individual system. Accordingly, HP urges that a portion of the 450-470 MHz band sufficient to meet the growing requirements for low power ECG and other medical telemetry systems be established for the primary operation of this essential life-saving technology.

Only after a protected band for low power medical telemetry technology is established can one sensibly consider a transition period for existing systems to be grandfathered (which must include protection from new sources of destructive interference) and new systems to be developed. It is HP's experience that hospitals often use products such as ECGs for 15-20 years. Given the increasing concerns regarding health care costs, there is no reason to believe that such period of anticipated use will be shortened. Balancing health care costs against other public interest benefits of refarming, HP urges that at least 10, and preferably 15 years be allowed for transition. However, as noted above, the time for transition cannot begin until there is a place in the band to which to migrate where medical telemetry technology can exist without suffering interference from other incompatible services.

⁸ 47 C.F.R. § 90.267(a)(7) adopted by Order, 7 FCC Rcd 5464 (1992). HP notes that there appears to be a typographical error in proposed 47 C.F.R. § 88.1299(b) that would permit mobile stations operating at 10 mW or less output power to do so without separate license authorizations. The Notice (¶26) proposes that delicensing apply to stations at 20 mW or less, which conforms with the exception that is applicable to hospitals.

VI. CONCLUSION

The Commission's refarming proceeding offers great promise for finally establishing an interference-free home for ECG and other essential life-saving medical telemetry technologies. HP urges that this promise be fulfilled.

Respectfully submitted,

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May 28, 1993

Before the FEDERAL COMMUNICATIONS COMMISSION Washington, D.C. 20554

In the Matter of)			
Replacement of Part 90 by Part 88 to Revise the Private Land Mobile))	PR	Docket	92-235
Radio Services and Modify the Policies Governing Them)			

To: The Commission

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May 28, 1993

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SUMMARY

SpaceLabs Medical, Inc. ("SpaceLabs"), is a pioneer in the design and manufacture of wireless electrocardiogram ("ECG") telemetry monitors. Its newest generation of monitors (along with those of other manufacturers) operate at extremely low power (e.g., less than 5 mW) on the offset channels in the 450-470 MHz band, and are widely used by hospitals to provide real-time monitoring of ambulatory cardiac patients.

In recent years, as spectrum congestion has increased, it has become exceedingly difficult to ensure the interference-free operation of these wireless ECG monitors, particularly in major urban areas. Thus, SpaceLabs generally supports any effort to reduce spectrum congestion and increase efficiency.

However, the new regulations for the offset channels set out in the Notice of Proposed Rulemaking ("NPRM") are so constraining that there is substantial doubt regarding the ability of future generations of ECG monitors to operate under that regime. As proposed in the NPRM: (1) offset channel bandwidths are far too narrow; (2) adjacent channel power levels are far too high; and (3) the new exclusive-use licensing concept creates financial incentives diametrically opposed to the continued availability of channel capacity for low power medical telemetry.

The wisest long-term solution would be the initiation of a proceeding to allocate new spectrum for the primary use of biomedical telemetry. It is highly likely that new spectrum will become available within the next several years (from the current

federal government pool) that could accommodate the unique needs of the industry. If the Commission were to begin an allocation proceeding now, it could complete that process well in advance of the conclusion of the refarming transition period. This would enable the biomedical telemetry users to amortize existing equipment and avoid the major dislocations that otherwise would be involved in attempting to meet the Part 88 regulatory scheme.

Before the FEDERAL COMMUNICATIONS COMMISSION Washington, D.C. 20554

In the Matter of)
Replacement of Part 90 by Part 88 to Revise the Private Land Mobile) PR Docket No. 92-235
Radio Services and Modify the Policies Governing Them	

To: The Commission

COMMENTS OF SPACELABS MEDICAL, INC.

SpaceLabs Medical, Inc. ("SpaceLabs") hereby submits its comments on the Notice of Proposed Rulemaking, 7 FCC Rcd. 8105 (1992) ("NPRM"), issued in the above-captioned proceeding. In general, SpaceLabs supports the Commission's efforts to increase the efficiency with which the various private radio services use the spectrum. The level of congestion and interference that some services must confront today borders on (and, in some instances, is) intolerable. It is essential, however, that the Commission craft its regulatory reforms with a deft touch, exhibiting sensitivity to the unique needs of hospitals and other major healthcare institutions which use a small portion of the spectrum under review in the NPRM for the provision of vital biomedical telemetry services.

I. SPACELAB'S INTEREST IN THE PROCEEDING.

For almost thirty years, SpaceLabs has been designing and manufacturing a broad array of specialized technical products for use by the medical community, including wireless electrocardiogram ("ECG") monitoring systems. SpaceLabs has been manufacturing these telemetry devices since the late 1960s,

initially using technology developed by the company while working with NASA on then-new biomedical telemetry systems for the manned spaceflight program.

SpaceLabs' early generations of ECG monitors (as well as those of other manufacturers) primarily operated in the VHF band, under the provisions of Part 15 of the Rules. See generally SpaceLabs, Inc., 26 F.C.C.2d 40 (1970); Laser Systems and Electronics, Inc., 26 F.C.C.2d 19 (1970). Eventually, the Commission established an exclusive reserve for biomedical telemetry operations under Part 15, on the vacant VHF television channels in the 174-216 MHz band. See 47 C.F.R. § 15.241; Biomedical Telemetry Radio Systems, 33 F.C.C.2d 880 (1972).

However, because of the severe restrictions on power levels inherent in Part 15 operations (which inhibit the industry's ability to compensate for the increasing levels of background noise in the VHF band), some companies also manufacture ECG monitors that operate on the offset channels in the 450-470 MHz band in the Business Radio Service. See 47 C.F.R. §§ 90.75, 90.217, 90.267. Indeed, in recent years, SpaceLabs has reached the conclusion that operation under Part 15 simply is not a viable longterm option, and has begun to concentrate its development efforts on the Part 90 offset channels. Thus, any changes to the relevant portions of Part 90 -- whether relating to allocations among services, eligibility or licensing matters, or technical considerations such as bandwidth or power levels -- could have a significant

impact on the vital medical services presently provided by these telemetry systems.

II. OVERVIEW OF WIRELESS BIOMEDICAL TELEMETRY.

A. System Functions and Capabilities.

An ECG monitoring system records and visually displays the electrical currents that stimulate the contraction of the heart muscle. The system measures that current by means of transducing electrodes attached to the patient's skin at various points on the body. Different electrode placements will generate different "views" of the heart. Irregular heart beats or other cardiac problems are identified by observing distortions in the electrical current represented by the ECG. To ensure accuracy, and to aid in identifying potential cardiac problems before they become acute, it is essential that the telemetry system provide multiple views of the heart. Each view requires a continuous, real-time data stream that must be absolutely error-free. latest generation of portable ECG monitors, using state-of-theart digital technology, requires a bandwidth of approximately 12.5 kHz (including guardbands) in order to provide two views of the heart.1/

Portability and cost considerations greatly reduce the flexibility that might otherwise be available to employ bandwidth reduction techniques such as multiple level encoding. The higher power levels required by such techniques mean larger, heavier batteries (or shorter battery life). Increased power also decreases frequency reuse capabilities and, in extreme cases, may pose a threat to patient health and/or to the operation of other electronic equipment frequently encountered in the hospital environment. In general (depending on variables such as building construction and terrain (continued...)

In any ECG monitoring system, the views of the heart collected by the electrodes must be transmitted to a central collecting point, where the data is converted to a visual image displayed on a monitor screen. In a wireless system, a small, portable unit (weighing approximately 7 oz.) is carried by the patient in a holster-style arrangement. The portable unit collects the data gathered by the electrodes and transmits them to an array of receiving antennas located in the ceiling of the corridors and other common areas of the hospital that are accessible to the patient. The signal is then carried via wire to a central point for processing and viewing, generally at a nurse's station.

Wireless ECG monitors provide both the hospital and the patient with vastly increased flexibility. Except for circumstances in which the patient is nonambulatory (e.g., in intensive care), it is logistically easier, and far more costeffective, to employ portable units. More importantly, the portable units permit ambulatory patients a great deal of freedom of movement, an aspect of the recovery process that has become increasingly important in the judgment of the medical profession. Shortened patient recovery periods provide substantial medical and financial benefits.

As noted above, biomedical telemetry has fairly rigid operational requirements. Communication must be (1)

^{1/(...}continued)
shielding), frequencies presently may be successfully
reused at 5,000 foot separations, which is a significant consideration in large urban medical centers.

instantaneous, (2) continuous, and (3) free from any interference that might cause a data error. The equipment must be sufficiently light in weight as to be easily carried by persons who, by definition, are not in the best physical condition. Because of considerations relating to patient safety and battery life, transmissions must be kept to relatively low powers. Of particular importance in this era of heightened concern over health care costs, the units must be sufficiently robust to withstand constant use without extensive maintenance, yet reasonable in price.

B. Current Frequency Availability.

The considerations listed above limit ECG monitors to operating within a fairly narrow band of the spectrum, <u>i.e.</u>, between 50 MHz and 1,000 MHz. Under the existing allocations, telemetry manufacturers essentially are restricted to one of two choices: unlicensed operation on vacant VHF television channels in the 174-216 MHz band under Section 15.241,² or operation on

Biomedical telemetry also is permitted on vacant UHF television channels under Part 15 in the 512-566 MHz band. See 47 C.F.R. § 15.209(g)(2); Revision of Part 15 of the Rules, 5 FCC Rcd. 2723, 2725 (1990). SpaceLabs is not aware of any manufacturer with a telemetry product that utilizes those frequencies. SpaceLabs believes that these channels go unused because the field strength limit imposed on operations in that band by Section 15.209(a) is far too low to permit reliable communications at economically viable prices.

Moreover, it would appear that the continued availability of this portion of the UHF band is in considerable doubt, given the Commission's stated preference for assigning most, if not all, high definition television ("HDTV") channels to that band. See Advanced Television Systems, FCC 92-332, released (continued...)

a secondary basis under Part 90, on certain of the 450-470 MHz splinter channels. See 47 C.F.R. §§ 90.75, 90.217, 90.267.

The existing Part 90 regulatory scheme permits:

(1) any type of telemetry operations on most of the 450-470 MHz offset channels; and (2) solely biomedical telemetry in hospitals or similar medical facilities on certain offset channels in the 460 and 465 MHz bands. See 47 C.F.R. §§ 90.75, 90.267.

Telemetry devices operating on the offset channels at no more than 20 mW output power are not required to be separately licensed, so long as the hospital or other medical facility in question is licensed by the FCC for other radio operations. See FCC News, Private Radio Action: Commission Eliminates Licensing Requirements for Low-Power Medical Devices in the 450-470 MHz Band, Report No. PR-81, released August 19, 1992. See also Public Notice, Private Radio Bureau Clarifies Licensing Procedures for Certain Low Power Devices, DA 92-665, released June 1, 1992.

The main problem that historically has confronted biomedical telemetry operations in the 450-470 MHz band (as well as in the VHF band under Part 15) is susceptibility to interference, which stems primarily from: (1) telemetry's very low operating power; (2) the limited number of channels available in any given locale, particularly in major urban areas where

August 14, 1992. Indeed, in those markets in which there is insufficient UHF capacity to meet all HDTV requirements, the Commission has proposed to use the existing VHF TV band, and thus a number of the vacant VHF channels presently available for biomedical telemetry in a given market may be eliminated.

high-power mobile use generally is extensive; and (3) telemetry's secondary status <u>vis-a-vis</u> those high-powered systems. As land mobile uses have increased during the past decade, interference problems have multiplied.

At present, there are approximately 280 splinter channels available for biomedical telemetry. Because telemetry systems must accept interference -- essentially without recourse -- from primary services, many of those 280 channels may be unavailable in a particular locale, depending on the nature of co-channel and adjacent channel operations. In many major medical centers, upwards of 250 telemetry channels may be in operation at any given time, thereby essentially exhausting the available supply in the 450-470 MHz band. If one or more channels are receiving interference from an outside source, there simply may not be an alternative channel available to which to move. 44

Indeed, seemingly viable splinter channels sometimes turn out to suffer from periods (however brief) of totally debilitating interference, based on the random meanderings of an adjacent channel licensee's high-powered mobile units. This sort of problem arises without warning, and can trigger a hospital staff response to a perceived (but nonexistent) life-threatening emergency.

For reasons of cost and to ensure proper operation, portable ECG monitors are not frequency-agile; each is tuned to a specific channel. Thus, moving to a new frequency to escape interference is not just a matter of flipping a switch or turning a dial. Changing frequencies requires that the first monitor be disconnected from the patient and a new one installed.

Increasing the power level (e.g., up to 20 mW) is not a panacea for the interference problem. Even assuming that the above-described patient safety, weight, and (continued...)

C. Next-Generation Telemetry Requirements.

The above-described difficulties are aggravated by the growing demands of the medical profession. First, the use of wireless telemetry is increasing rapidly, particularly given the medical and financial benefits of expedited recovery periods. Wireless ECG monitors make a substantial contribution toward achieving both of those goals, and SpaceLabs' long-term plans envision that, within the decade, it will not be uncommon for a major medical center to simultaneously monitor upwards of 500 patients using wireless telemetry systems.

Second, the medical profession increasingly is demanding additional patient data from portable systems.

Upcoming generations of monitors most likely will provide three views of the heart (instead of the current two), plus information on other patient parameters such as blood pressure, blood gas, and respiration. Each parameter will require an independent data stream.

Within the last few years, advances in digital technology have permitted the use of somewhat narrower bandwidths per
data stream, but these advances are being offset by the increased
number of patient parameters sought by the medical profession.
Moreover, this trend takes place within the context of an

 $[\]frac{4}{3}$ (...continued)

cost parameters still could be met, using significantly higher powers than the existing 2-4 mW output levels would create different concerns: (1) the telemetry signal no longer would be generally confined by the hospital's walls, which could result in interference to primary services; and (2) frequency reuse capabilities would be decreased, which is an important consideration in congested urban areas.

increasingly polluted electronic environment, as more and more advanced electronics technology is relied on by the medical profession for diagnostic and treatment purposes, in addition to the increase in the number of personal computers and peripherals used for general administrative tasks.

As is discussed below, the refarmed spectrum to be governed by Part 88 appears to create substantially more splinter channels for biomedical telemetry use. However, this potential increase may prove to be quite illusory, at least as the regulatory scheme presently is proposed.

III. IMPACT OF THE "REFARMING" PROPOSALS.

A. The Proposed Regulatory Structure.

Section 88.1299 of the FCC's proposed rules would, if adopted, provide as follows:

- (a) Low-power mobile stations of 100 mW or less output power may be assigned any frequency separated by 3.125 kHz from a regularly assigned frequency in the 460.646875-460.878125 MHz and 465.646875-465.878125 MHz bands listed in Subpart D, for one-way, non-voice biomedical telemetry operations in hospitals, or in medical or convalescent centers.
- (b) Low-power mobile station of [20 mW⁵] or less output power may be assigned for telemetry operation on any frequency separated by 3.125 kHz from a regularly assigned frequency in the 450-470 MHz bands listed in Subpart D. Licensees need not

As set out in the NPRM, proposed Section 88.1299(b) establishes a 10 mW limit on output power. However, it is SpaceLabs' understanding, based on informal discussions with the staff of the FCC's Private Radio Bureau ("PRB"), that the reference to 10 mW is a typographical error which will be corrected to 20 mW in the eventual Report and Order.

obtain a separate authorization for such operation. Such operations will be on a secondary basis.

See NPRM at 278.

It appears from proposed Sections 88.907(a) (NPRM at 238) and 88.1293 (NPRM at 277) that the Commission intends to maintain its existing policy of restricting all splinter channel operations to secondary status. 6/ Thus, the impact of proposed Part 88 on this health-care service appears limited to the following: (1) the availability, over time, of more offset channels for telemetry (some at up to 100 mW power), created as a consequence of channel splitting; and (2) a reduction in some 450-470 MHz main channel power levels, thereby theoretically reducing the likelihood of interference from adjacent full-power In the abstract, these changes might appear operations. In fact, however, the proposed modifications to the beneficial. existing regulatory framework represent a substantial threat to the longterm viability of biomedical telemetry services.

B. The Proposed Reduction In Offset Channel Bandwidth Will Have A Substantial Adverse Impact On Biomedical Telemetry.

Section 88.1299 and Subpart D of proposed Part 88 would establish offset channels in the 450-470 MHz band, separated by

However, by placing an explicit secondary service restriction in Section 88.1299(b), an inference arises that operations under Section 88.1299(a) would be considered primary. If this interpretation is correct -- which would create at least a limited number of primary service channels for biomedical telemetry in the 460 and 465 MHz bands for the first time -- this would represent a modest but potentially significant improvement over the status quo. It is important that further clarification be provided regarding this matter.